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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 21

Application Number: 09/646,355
Filing Date: November 16, 2000
Appellant(s): SCHMIDT ET AL.

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EXAMINER'S ANSWER

This is in response to the appeal brief filed December 23, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 17-24 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

WO 96/08231 Messenger 3-1996

Brodie et al., "Aromatase Inhibitors III. Studies on the Antifertility Effect of 4-Acetoxy-4-androstene-3,17-dione", Biol. Reprod. 1978, 18(3):365-370.

Hanson, Remington: the Science and Practice of Pharmacy, 19th ed., 1995, page 1218.

(10) Grounds of Rejection

The Appellant's arguments with regard to the outstanding rejections under 35 USC 112, second paragraph are found persuasive to withdraw the outstanding rejections under 35 USC 112, second paragraph rejections of claims 17-24.

The following ground(s) of rejection are applicable to the appealed claims:

Claims 17-24 are rejected under 35 U.S.C. 103(a). This rejection is set forth in prior Office Action, Paper No. 13.

(11) Response to Argument

Examiner finds unconvincing Appellant's rebuttal arguments presented on page 8 bridging to page 9 averring a patentable distinction residing in the preambles, and the intended purpose, envisioned for the compositions produced by the claimed methods (i.e., so as to avoid systemic action of the active ingredient). These arguments are flawed in two ways.

Firstly, examiner notes that the instant claims are drawn to a method of making a composition comprising an aromatase inhibitor without antiestrogens and a penetration enhancer. Moreover, examiner notes the claims fail to recite any specific steps for making or preparing the envisioned composition, or any specific limitations as to employing a particular penetration enhancer. Absent specific step recitation, one of

ordinary skill in the art would see a method of making the herein claimed composition as a simple mixing of old and well known components, thus, reading on the product comprising the same components. Without reciting a specific penetration enhancer, the claims essentially encompass all penetration enhancers known in the pharmaceutical art. The cited prior art, teaching penetration enhancers generally, renders obvious compositions containing such ingredients. Examiner directs attention to the Dillon ruling where the court sitting *in banc* ruled that the recitation of new utility for an old and well-known composition does not render that composition new (See *In re Dillon* 16 USPQ 2d, 1897 at 1900 (CAFC 1990)). The mere mentioning of intended treatment or prophylaxis use as herein recited fails to provide a distinguishing claim limitation, unless that amount is different from the prior art and critical to the use of the claimed composition (See *In re Dillon* 16 USPQ2d 1897 at 1902). A specific aromatase inhibitor or a specific amount of aromatase inhibitor was not necessary recited in the claims 17 or 20-24. Examiner notes the dependent claim 23 and 24 provide active ingredients levels of 0.6-10% and 1-5% respectively. The cited prior art, Messenger, teaches the range of the preferred aromatase inhibitor as 0.2 – 10% (See Messenger, page 28, Example 1). The herein claimed amount of the active ingredient and that of the cited prior art overlap, thus, are not significantly different. Moreover, examiner notes the criticalities of the specific narrowed amount have not been demonstrated. Absent a showing of criticality in the claimed composition, one of ordinary skill in the art would, incorporate the herein claimed components into a single composition based on the prior art use of these compounds individually for the same purpose.

Secondly, as cited by the appellant in page 9 of the appeal brief, it is well-settled in the case law that "If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation" [emphasis added] See *Rowe*, 112 F.3d at 478, 42 USPQ2d at 1553; *Corning Glass*, 868 F. 2d at 1257, 9 USPQ2d at 1966; *Kropa*, 187 F.2d at 152,88USPQ at 480-81. In the instant case, the claims fail to recite specific steps or specific agents to achieve the herein claimed characteristics, but merely recite the envisioned compositions' purpose and intended use (i.e., for the treatment or prophylaxis of mastocarcinoma). Therefore, merely reciting such characteristics, or intended use, fail to further explain or limit the invention as herein claimed.

Appellant's rebuttal arguments on pages 9 and 10 averring examiner's failure to provide motivation to combine the cited prior art recited substance as promoting skin penetration for the claimed active ingredient are not convincing. As discussed above, the instant claims are drawn to a method of making the herein claimed composition. A recited purpose or intended use fails to further distinguish the herein claimed inventions because the active ingredient levels taught in the prior art are essentially the same as those herein claimed. Examiner notes no specific penetration enhancer is recited in the broadest claim. Absent a showing of criticality residing in the levels of penetration enhancer herein claimed, one of ordinary skill in the art possessing the examiner cited

prior art teachings would therefore be motivated to incorporate the old and well known prior art penetration enhancer herein claimed, DMSO, into the topical composition of Messenger thereby enhancing the systemic absorption of the active agent. This motivation would be based on DMSO's old and well known topical penetration enhancing activity.

Examiner finds unconvinced Appellant's rebuttal arguments on pages 10 - 12 of the appeal brief averring the cited prior art's failure to teach the method of treating mammary carcinoma. Examiner notes the instant claims are drawn to a method of making a composition comprising an aromatase inhibitor without antiestrogens and a penetration enhancer. The instant claims are not drawn to a method of treating mammary carcinoma. Appellant's claims recite neither any specific steps for making the herein claimed composition, nor any specific limitations as to employing the particular penetration enhancer. Absent specific ordered steps directing the making of a composition, one of ordinary skill in the art would see such a method of making as herein recited as a simple mixing of the old and well known components together and, thus, reading on the product comprising the same components.

Without reciting a specific penetration enhancer, the claims essentially encompass all penetration enhancers known in the pharmaceutical art. The cited prior art, as a whole, teaches aromatase inhibitors, and penetration enhancers, such as DMSO as old and well known for the same purpose. Examiner notes that the court sitting *in banc* ruled that the recitation of new utility of old and well-known composition does not render that composition new (See *In re Dillon* 16 USPQ 2d, 1897 at 1900

(CAFC 1990)). Mere mentioning of a treatment or prophylaxis use is not a distinguishing claim limitation, unless that amount is different from the prior art and critical to the use of the claimed composition (See *In re Dillon* 16 USPQ2d 1897 at 1902). A specific amount of the aromatase inhibitor was not recited in the broadest claim. Dependent claims 23 and 24 recite the active ingredient levels as 0.6-10% and 1-5% respectively. Messenger, cited by the examiner, teaches the range of the preferred aromatase inhibitor as 0.2 – 10%, which overlaps those envisioned by Appellant (See Messenger, page 28, Example 1). The herein claimed amount of the active ingredient and that of the cited prior art are not significantly different. Moreover, these criticalities hypothesized by Appellant as residing in the specific narrowed amount herein envisioned have not been demonstrated. Absent showing the criticality, one of ordinary skill in the art would therefore, incorporate the herein claimed components into a single composition.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

San-ming Hui
March 7, 2003

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